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10/066,054	01/31/2002	Dorin Panescu	267/107	3947

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EXAMINER
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PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 10/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/066,054

Applicant(s)

PANESCU, DORIN

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Applicant's amendments and comments, received August 21, 2003, have been fully considered by the examiner. The following is a complete response to the August 21, 2003 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is unclear as to the scope of the claim. The preamble recites "A system for delivering power to a therapeutic device" which suggests that the system does not include the therapeutic device. However, the therapeutic is then positively recited in the body of the claim with the limitation "a feedback apparatus coupled to one or both of the patient cable and the therapeutic device". It is therefore unclear if the applicant is claiming the system, or the combination of the system and the therapeutic device. Subsequent dependent claims (i.e. claims 7-10) also positively recite the therapeutic device making it apparent that the combination of the system and the therapeutic are to be the scope of the invention. It is suggested that the preamble be amended to positively recite the therapeutic device (e.g. "A system including a therapeutic device").

***Claim Rejections - 35 USC § 102***

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Claims 1-3, 7, 8, 11, 12, 14, 16-18, 21, 24, 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Strul et al ('681).

Strul et al discloses a system including an ablation catheter (12) and a means for controlling the delivery of energy to the RF electrodes of the catheter. The system includes a generator (18), a patient cable (22) connecting the catheter to the generator via connector (24). There is also a feedback apparatus (30) coupled to the therapeutic device. The feedback apparatus is a temperature sensor and senses a variable (i.e. temperature) which is dependent on the delivered power. A feedback signal from the feedback apparatus is used to control the output power of the generator. Wires (22b) provide the feedback path for transmitting the feedback signal back to the power generator in the form of an analog signal. The method of using the device is inherent to the structure and fully disclosed by Strul et al.

Claims 1-5, 11, 12, 14, 16-21, 24, 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Becker et al ('659).

Becker et al disclose a system which includes a generator (101) including a power regulation circuit (109) and patient cables connecting the generator to therapeutic electrodes (111). Also, there is a feedback apparatus connected to the patient cable (see Figure 1). The feedback apparatus is inductively coupled to the therapeutic electrodes (col. 5, lines 40-45) or may be connected in circuit to the electrodes and is used to sense voltage and current in order to control the delivery of power to the

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electrodes. A wire connects the feedback apparatus to the generator. The method of using the system is inherent to the structure and fully disclosed by Becker et al.

***Claim Rejections - 35 USC § 103***

Claims 4-6, 15, 19, 20 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strul et al ('681) in view of the teaching of Becker et al ('659).

The Strul et al system has been addressed previously. In addition to the temperature sensors, Strul et al teach that the voltage, current and power may be monitored and that information used to control the output power of the generator (col. 2, line 65 to col. 3, line 5). However, Strul et al do not teach of providing the current/power/voltage sensor means located on the therapeutic device as set forth in the instant claims. Also, Strul et al fail to disclose the use of digital signals from the feedback apparatus (i.e. sensors).

Becker et al, as addressed previously, disclose a power/voltage/current measurement means which may be connected to the therapeutic device either inductively or by direct circuit. Such an arrangement allows for the measure of the voltage, current and power characteristics at the device. Further, Becker et al suggest that the components may be either digital or analog (Abstract) as is well known in the art. It is the examiner's position that one of ordinary skill in the art would recognize the obvious substitutability of analog and digital sensors.

To have provided the Strul et al system with a voltage/current sensor feedback means connected to the therapeutic apparatus (i.e. catheter) in order to monitor the

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current, voltage and power characteristics at the device (rather than at the generator) would have been an obvious modification for one of ordinary skill in the art in view of the Becker et al teaching.

Claims 9, 10, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strul et al ('681) in view of the teaching of Brucker et al ('012).

The Strul et al system has been previously addressed. Strul et al provide an RF ablation catheter for the treatment of tissue, and fail to disclose the use of alternate energy sources such as microwave and ultrasonic energy.

Brucker et al also disclose an ablation catheter system which includes an RF electrode means for treating tissue and a temperature feedback means to control power delivery. Also, Brucker et al teach that it is generally known to substitute other types of energy modalities, such as microwave and ultrasonic energy (col. 2, lines 50-56). The examiner maintains that the use of well-known alternative energy delivery means is generally known in the art as evidenced by Brucker et al.

To have provided the Strul et al system with any well-known alternative energy source, such as microwave and/or ultrasonic energy, would have been an obvious consideration for one of ordinary skill in the art, particularly since Brucker et al teach that these energy modalities are readily substitutable in ablation catheter systems.

Claims 13 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strul et al ('681) in view of the teaching of Ben-Haim ('493).

Strul et al fail to disclose the use of wireless sensors which transmit measured data to a central control without a hard-wired connection.

Ben-Haim disclose an endoscope system which employs a plurality of sensors for monitoring endoscope position. In particular, Ben-Haim teach that the sensors may be hard-wired to the control unit, or the sensors may be use wireless transmitters so as to take up less space in the device with sensor wires (col. 9, lines 45-50).

To have provided the Strul et al sensors with a wireless transmission means to send the sensed data to the controller while taking up less space with transmission wires would have been an obvious design consideration for one of ordinary skill in the art, particularly since Ben-Haim teach that wireless sensors may be advantageously employed to provide signals while taking up minimal space in a catheter-type device.

### ***Response to Arguments***

Applicant's arguments filed August 21, 2003 have been fully considered but they are not persuasive.

With regard to the 35 USC 112, second paragraph rejection, the examiner maintains that the claims remain unclear with the scope of the claims. It is noted that claim 1 was specifically rejected and applicant has attempted to remedy this issue by amending claim 7. The indefiniteness with the scope of the claims stems from the Claim 1 preamble recitation of "A system for delivering power to a therapeutic device" (emphasis added). The underlined portion indicates that the therapeutic device is not being positively claimed and that use of the system with a therapeutic device is merely a

statement of intended use. However, the body of claim 1 goes on to positively recite a feedback apparatus coupled to the therapeutic device. Applicant is required to either establish in the preamble of Claim 1 that the therapeutic device is part of the system (e.g. "A system including a therapeutic device comprising") or remove the positive recitation of the therapeutic device from the body of claim 1. As amended, claims 7-10 continue to make unclear the scope of the claims since these claims further limit the therapeutic device even though claim 1 is unclear if the therapeutic device is a positive feature of the claim.

Applicant asserts that Strul et al do not disclose or suggest a power regulation circuit which is "configured for compensating a power change along the patient cable by controlling the output power based at least in part on the feedback signal". The examiner disagrees. The Strul et al sensors are temperature sensors which are related to the power delivered by the system. That is, as more power is delivered, more heat is generated and the temperature sensors respond to a change in measured temperature to control the output of the generator. Should a power change along the cable be present, the sensors will continue to control the output of the generator based on the measured temperature. Hence, the Strul et al system is clearly "configured" to compensate for power changes along the patient cable by controlling the output power based on a feedback signal. For instance, if the power is at level "A" at the generator, and the power is at level "B" (which is less than "A") at the end of the cable, the temperature sensor is still responding to the temperature at the end of the cable and controls the output of the generator accordingly even though the sensor is itself



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unaware of the power change along the cable. It is noted that applicant's claims do not recite a specific means for measuring or otherwise detecting a power change along the cable. As broadly written, the newly added claim language merely require the power regulation circuit to compensate for a power change, even if the system is doing so without recognizing that a power change has occurred.

Similarly, applicant contends that Becker et al do not disclose a power regulation circuit which is configured for compensating a power change along the patient cable by controlling the output power based on a feedback signal. Again, the examiner maintains that the sensed parameter of Becker et al, which is current, will compensate for power changes along the by maintaining measured values at the sensors within an acceptable range. Like Strul et al, the Becker et al system does not monitor or measure power changes along the length of the cable, but the applicant's claims do not specifically recite the structure for determining a power change nor preclude the use of prior art which may inadvertently account for such changes in power along the cable length in its feedback control.

Applicant's arguments with respect to claims 6 and 20 are based solely on the position that the Strul et al and Becker et al systems did not anticipate the claim language. The examiner maintains that the 35 USC 102 rejections of the claims with these two references are tenable and are maintained, as are the 35 USC 103 rejections. Applicant failed to specifically address the 35 USC 103 rejection of claims 9, 10, 22 and 23 which were rejected with the combination of the Strul et al and Brucker et al

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references and the 35 USC 103 rejection of claims 13 and 26 rejected with the combination of the Strul et al and Ben-Haim references.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

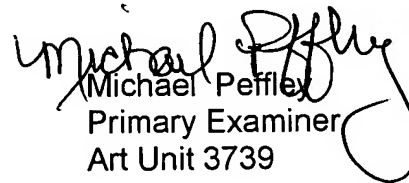
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

  
Michael Peffley  
Primary Examiner  
Art Unit 3739

mp  
October 13, 2003